

## **II. REMARKS**

### **A. Status of the Claims**

Claims 1-28 and 31-51 were pending in the case at the time of the Office Action, with claims 3-5, 8-28, and 34 having been previously withdrawn from consideration. Claims 52-59 have been previously canceled without prejudice or disclaimer.

Regarding the amendments, claims 1 and 2 have been amended to recite the tumor angiogenesis targeting ligands set forth in claim 4, the specific disease cell targeting ligands set forth in originally filed claim 7, the specific tumor apoptosis targeting ligands set forth in claim 9. Claims 1, 2, and 5 have been amended to recite "COX 2 inhibitor." Support for the amendments to the claims can be generally found throughout the specification, such as in the claims as originally filed, and on page 6, line 23 ("COX 2 inhibitor"). Claims 3, 4, and 6-9 have been canceled without prejudice or disclaimer. Claims 10 and 11 have been amended to depend from claim 1. Thus, claims 1, 2, 5, 10-28, and 31-51 are currently under consideration.

### **B. The Double Patenting Rejections Are Overcome or Addressed**

#### **1. The Rejections Under 35 U.S.C. §101 Based On U.S.S.N. 10/703,405 Are Moot**

According to the Action, Claims 1, 2, 6, 7, 31-33, and 35-51 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as claims 1, 2, 5, 6, 27-29, and 31-47 of copending application No. 10/703,405. Applicants have abandoned copending application No. 10/703,405. Therefore, this provisional rejection is moot.

#### **2. The Nonstatutory Obviousness-Type Double Patenting Rejections Are Overcome**

Claims 1, 2, and 31-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent 6,692,724. Claims 35-41

are rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-5 and 7 of U.S. Patent 7,067,111. Applicants respectfully traverse. It is respectfully submitted that in view of the amendment set forth herein, none of the targeting ligands are of overlapping scope with those set forth in the '724 patent or the '111 patent.

Claims 35-41 are rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-5 and 7 of U.S. Patent 7,067,111. Applicants respectfully traverse. It is respectfully submitted that in view of the amendment set forth herein, none of the targeting ligands are of overlapping scope with those set forth in the '724 patent or the '111 patent.

**3. The Provisional Rejections Based On Nonstatutory Obviousness-Type Double Patenting Will Be Addressed When The Rejections Are No Longer Provisional**

Claim 38 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-73 of copending application No. 10/672,763. Claims 42-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-50 and 74-81 of copending application 11/405,334. Applicants understand that these rejections are only provisional. Applicants respectfully traverse these provisional rejections. It is respectfully submitted that in view of the amendment set forth herein, none of the targeting ligands are of overlapping scope with those set forth in application 10/672,763 or application 11/405,334.

**C. The Rejections Under 35 U.S.C. §112, First Paragraph, Are Overcome**

Claims 1, 2, 6, 31-33, and 35-51 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while said to be enabling for certain specific targeting ligands, is said to not reasonably provide enablement for “a disease cell cycle targeting compound” or a “disease receptor targeting ligand.” Furthermore, these claims are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the

specification is said to lack adequate written description support for these phrases. The Examiner appears to concede that there is written description support for the specific examples of such ligands recited in the specification. Applicants respectfully traverse.

Without conceding that the claims as originally written are not enabled by the instant specification, Applicants note that the claims have been amended to omit reference to “a disease cell cycle targeting compound” or a “disease receptor targeting ligand.” Therefore, these rejections are moot.

Applicants do not disclaim any claimed subject matter that makes reference to “a disease cell cycle targeting compound” or a “disease receptor targeting ligand,” and reserve the right to prosecute such subject matter in a divisional or continuation application.

**D. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome**

Claims 1, 2, 31-33, and 35-51 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner argues that the phrases “a disease cell cycle targeting compound” and “a tumor apoptosis targeting ligand” render the claim indefinite because of overlap in scope. Applicants respectfully traverse.

Without conceding that the claims as originally written were indefinite, Applicants note that the claims have been amended to omit reference to “a disease cell cycle targeting compound” and “a tumor apoptosis targeting ligand.” Therefore, this rejection is moot.

Applicants do not disclaim any claimed subject matter that makes reference to “a disease cell cycle targeting compound” or a “tumor apoptosis targeting ligand,” and reserve the right to prosecute such subject matter in a divisional or continuation application.

**E. The Rejections Under 35 U.S.C. §102 Are Overcome**

Claims 1, 2, 31-33, 35-49, and 51 are rejected under 35 U.S.C. §102(b) as being anticipated by Yang et al. (WO 01/91807; hereinafter “Yang”). Applicants respectfully traverse.

Yang fails to anticipate the claimed invention because it does not expressly or inherently disclose each limitation of the claimed invention. More particularly, it fails to set forth any of the tissue specific ligands set forth in the present claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Because Yang fails to describe each limitation of the claimed invention, there can be no anticipation of the pending claims. Therefore, Applicants request withdrawal of the rejection under 35 U.S.C. §102 based on Yang.

**F. The Claim Rejections Under 35 U.S.C. §103 Are Overcome**

Claims 1, 2, 6, 7, 31-33, and 35-51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Iyer *et al.* (J. Nucl. Med., 2001, 42, p. 96-104; hereinafter “Iyer”) in view of Yang (as above). Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (3) there must be a reasonable expectation of success. *Manual of Patent Examining Procedure* § 2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991) (emphasizing that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior

art, and not based on applicant's disclosure). It is important to note that all three elements must be shown to establish a *prima facie* case of obviousness.

In the present case, there is no *prima facie* case of obviousness because the cited combination of references fails to teach or suggest each limitation of the claimed invention. In particular, the cited combination of references fails to teach or suggest those tissue specific ligands set forth in the presently pending claims. Iyer has been cited as teaching or suggesting penciclovir as a targeting ligand. However, none of the claims as written pertain to penciclovir as a targeting ligand.

Furthermore, one of ordinary skill in the art would not be motivated to provide for any of the claimed compounds based on the teachings of Iyer and Yang. Iyer pertains to [18F]Fluoropenciclovir, and not any of the targeting ligands set forth in the instant claims. Applicants do not identify any teaching or suggestion in these references to provide for the claimed compounds or methods, and invite the Examiner to review these references to identify any such teaching or suggestion. In accordance with *In re Vaeck*, in the absence of any teaching or suggestion to provide for the claimed compounds and methods, there can be no *prima facie* case of obviousness.

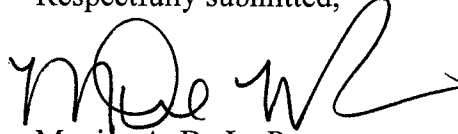
In view of the foregoing, claims 1, 2, 6, 7, 31-33, and 35-51 are not unpatentable under 35 U.S.C. §103(a) based on Iyer in view of Yang. Therefore, it is respectfully requested that this rejection should be withdrawn.

#### **G. Conclusion**

In view of the foregoing, it is respectfully submitted that each of the claims is in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is

invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'M. De La Paz', with a long horizontal flourish extending to the right.

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